

## **REMARKS**

### **FORMAL MATTERS:**

Claims 64, 69-72, 74, 75, 77, 78, 80-84, 86-90, and 110-136 are pending after entry of the amendments set forth herein.

Claims 1-63, 65-68, 73, 76, 79, 85, and 91-109 are canceled without prejudice.

Claims 64, 69-72, 74, 75, 77, 78, 80-84, 86-90, 110 and 111 are amended. Support for these amendments is found throughout the specification, as well as in the claims as originally filed (see, e.g., claims 64 and 68 as previously presented). Additional support is found in the specification at, for example, paragraph [0030] (claim 111).

New claims 112 -138 are added. Support for these new claims is found throughout the specification, as well as in claims 64, 70-92, 105-108, and 110-146 as previously presented. See also the specification at paragraphs [0039].

No new matter has been added.

### **INTERVIEW SUMMARY**

Applicants are grateful to Examiner Ton and Examiner Shukla for the in-person interview conducted with the undersigned and with Bart Wise, representative for the licensee. During the interview, a set of amended claims was presented which set out the amendments to claim 1 presented here, as well as new independent claim 113 and claims dependent thereon.

The present amendment seeks entry of these amendments, and provides further clarifying amendments discussed during the interview.

### **CERTIFIED COPY OF FOREIGN PRIORITY APPLICATION**

Applicants submit herewith a certified copy of the UK priority application serial no. 9824306.6, filed November 5, 1998. Applicants respectfully request the Examiner acknowledge that the foreign priority claim has now been perfected.

**OBJECTION TO THE SPECIFICATION**

The replacement specification submitted with the prior response to provide the published PCT application reformatted in accordance with current USPTO practice. However, the Office Action indicates the substitute specifications filed 2/12/03 and 11/23/05 have not been entered because they did not conform to 37 CFR §1.125(b).

A review of the file history of the present application indicates that, as suggested above, Applicants undertook filing of a replacement specification in response to the Office Action mailed August 6, 2002 in which the Office set out an objection to the specification for failure to provide the format described in 37 CFR §1.77(b). Specifically, the Office Action noted that the specification did not contain the desired section headings.

As discussed during the Interview, the elements of an application, the order of the sections in the specification, and the use of section headings are not mandatory. Specifically, 37 CFR §1.77 states:

**§ 1.77 Arrangement of application elements.**

(a) The elements of the application, if applicable, **should** appear in the following order:

\* \* \*

(b) The specification **should** include the following sections in order:

\* \* \*

(c) The text of the specification sections defined in paragraphs (b)(1) through (b)(12) of this section, if applicable, **should** be preceded by a section heading in uppercase and without underlining or bold type.

The use of “should” throughout 37 CFR §1.77 indicates that this format *should* contain these, not that the specification *must* contain these elements, sections, and section headings.

As confirmed during the Interview, the amendments to the specification requested in Preliminary Amendment filed May 4, 2001 were entered by the Office. Other than these amendments, the only other specification amendments in the earlier submitted replacement specifications were to address the objection under 37 CFR §1.77. Accordingly, as discussed during the Interview, filing of a new replacement specification appears not to be necessary nor required, and no replacement specification is submitted with this amendment.

Applicants respectfully request the Examiner withdraw any objection to the specification under 37 CFR §1.77, and indicate that a replacement specification is not necessary.

**REJECTIONS UNDER §112, ¶1**

Claims 64, 68-95, 105-108, 110 and 111 were rejected under §112, ¶1 on the grounds that, while enabling for culturing mouse or human ES cells *in vitro* in the presence of IL-3, the specification was not enabling for culturing these cells in the presence of any cytokine or combination of cytokines. This rejection is traversed as applied and as it may be applied to the pending claims.

Each independent claim as now presented recites that the mouse or human ES cells are cultured in the presence of a composition comprising IL-3. In addition, the claims as presented make clear that human dendritic cells are made from human ES cells, and the mouse dendritic cells are made from mouse ES cells. In addition, the human and mouse claims are provided in separate independent claims, as kindly suggested by Examiner Ton. Applicants respectfully submit that this rejection is now rendered moot.

Withdrawal of this rejection is respectfully requested.

**REJECTIONS UNDER §112, ¶2**

Claims 81-83 and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the rejections as specifically applied to the claims is addressed below.

Claim 81 was rejected for lack of antecedent basis for “the gene”. This has been addressed by amendment of claim 81 to recite “the heterologous gene”. Withdrawal of this rejection is respectfully requested.

Claim 82 was rejected on the grounds that it is unclear what cell has an inactivated endogenous gene(s) -- the ES cell or the immature dendritic cell. Claim 83 depends from claim 82, and so was similarly rejected. This rejection has been addressed by amendment of claim 82, and thus may be withdrawn.

Claim 90 was rejected on the grounds that the claim recites that the recovered cell is “substantially pure”, which term the Examiner found to be unclear since “The recovery of a cell (as recited by the claim) would be considered only cell type, because the recovered cell is a single cell. It is unclear how a single cell could not be ‘substantially pure’.” This rejection has been avoided by amendment of claim 90 to recite that substantially pure refers to “dendritic cells”.

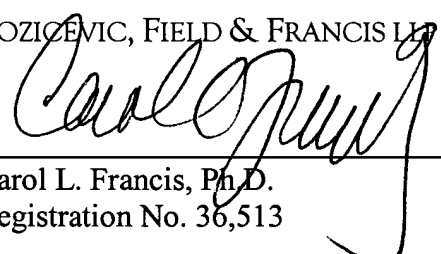
Withdrawal of the rejections of the claims under §112, ¶2 is respectfully requested.

**CONCLUSION**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number ISIS-001CON.

Date: Nov 15, 2006

Respectfully submitted,  
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